

CUSTOMER NUMBER 25268

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Christopher Toly

Attorney Docket No: SIMU0008

Serial No: 10/672,274

Group Art Unit: 3715

Filed: September 24, 2003

Examiner: Hadizonooz, Banafsheh

Title: LAPAROSCOPIC AND ENDOSCOPIC TRAINER INCLUDING A DIGITAL CAMERA
DECLARATION UNDER 37 C.F.R. 1.132

Bellevue, Washington 98004

January 21, 2009

TO THE DIRECTOR OF THE PATENT AND TRADEMARK OFFICE:

The following declaration of Christopher Toly is submitted as part of a response to an Office Action dated March 16, 2006.

1. I, Christopher Toly, the CEO of SimuLab Corp. am the sole inventor of the above-identified patent application, and as such, am familiar with the subject matter disclosed and claimed therein. I am also familiar with a commercial embodiment based on the invention described and claimed in that patent application, which is sold under the trademark SIMUVISION™.

2. The commercial embodiment, which is based on the invention and is substantially configured as described in the specification and defined in the claims of the above-identified patent application, was initially released into the marketplace in late 2003, and was very well received. Specifically, FIGURES 2, 3, and 4 of the application as filed correspond to the commercial embodiment, which includes a housing with an opening for surgical tools, a simulated laparoscope including a boom (note the terms boom, shaft, and elongate member have been used interchangeably in this declaration and the application) passing through the opening, the boom connecting a handle (which looks like an actual laparoscope handle) to a digital camera attached to a distal end of the boom, and a support structure enabling the digital camera to be moved in the practice volume. The simulated laparoscope, the tools, the opening, and the support structure are disposed such that a user can access all of them without moving from the front of the trainer. The cable from the digital camera passes through the boom and handle, so that from a user's perspective the trainer looks like it is using a real laparoscope (a very expensive medical tool including optical fibers passing from an external camera through the handle to the distal end of a boom/shaft). The commercial embodiment thus incorporates a digital video camera (i.e., a web camera) coupled to the distal end of the boom into an existing pop-up trainer, already configured for laparoscopic skills training (albeit without the

1 imaging capability afforded by the digital video camera). Due to its relatively large size, particularly
2 as compared to the distal end of a conventional laparoscope, the web camera is not encapsulated
3 within the boom, but is instead attached external to the boom, at the distal end of the boom. The
4 trainer was initially sold without a display, and has been used with great success by medical
5 professionals and medical students, who typically attach the web camera to a desktop or laptop
6 computer during training. Later models were sold with a laptop, so the user did not need to provide
7 the computer. Several key features have made this trainer particularly successful. First, the images
8 displayed are a highly realistic simulation of images that would be displayed by an actual
9 laparoscope. Second, the substitution of a web camera for a true laparoscope enables a very
10 inexpensive, yet high-quality trainer to be achieved. Laparoscopes are very sophisticated and very
11 expensive pieces of medical equipment. An inexpensive trainer that is configured to be used with
12 ubiquitous computing devices already present in medical offices and educational environments can
13 be much more widely distributed than a training device requiring the use of a relatively expensive
14 laparoscope camera. While web cameras are relatively inexpensive and work perfectly in the
15 SIMUVISION™ simulator, they are entirely unsuitable for use in an actual laparoscope because of
16 their size (i.e., they are entirely too large for insertion into a body via minimally invasive surgery).
17 Third, the web camera is integrated into a simulated laparoscope, including a handle that looks like
18 an actual laparoscope. The data cable from the digital camera extends through the boom, which
19 extends between the digital camera and the handle. The data cable passes through the handle, and the
20 portion of the data cable visible to the user extends from the rear of the handle to the
21 display/computing device (thus, from the user's perspective, when the digital camera is not visible,
22 the simulated laparoscope looks like a real (and very expensive) laparoscope). Indeed, at a trade
23 show where the product was introduced, laparoscopic surgeons and medical educators kept asking
24 how SimuLab could sell a training tool including a real laparoscope for such a low price. Fourth, the
25 trainer is easy to use, as the simulated surgical tools, the simulated laparoscope, and the support
26 structure for moving the digital camera are all accessible when the user is in front of the trainer, so
27 the user does not need to move from that location when using the trainer.

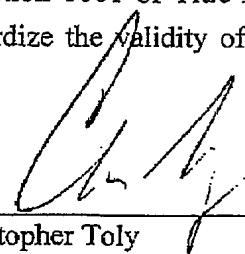
28 3. In recognition of the commercial embodiment's ability to meet a long felt need for an
29 inexpensive yet high-quality laparoscopic trainer, the commercial embodiment received the 2004
30 Innovation of the Year Award from the National Society of Laparoendoscopic Surgeons. A
fundamental goal of the Society is ensuring that its members have access to the newest ideas and
approaches, as rapidly as possible. The Innovation of the Year Award is designed to draw particular
attention to products that appear to have widespread appeal to Society members. A copy of the
award is attached. The following patents describe several trainers that were already in the
marketplace before the award was presented: U.S. Patent No. 5,722,836 and U.S. Patent

1 No. 6,659,776.

2 4. In summary, the invention claimed in the above-identified patent application, U.S.
3 Serial No. 10/672,274, provides a realistic training simulation at a much lower cost than could be
4 achieved using training simulators incorporating an actual laparoscope. The product has been very
5 well received by laparoscopic and endoscopic surgeons, as evidenced by the 2004 Innovation of the
6 Year Award noted above. Further, in my opinion, the present invention meets a long felt need for an
7 inexpensive surgical simulator that realistically simulates video endoscopic procedures. An
8 inexpensive trainer is critical, because vendors of endoscopic surgical tools and training institutions
9 cannot make wide use of surgical trainers that require relatively expensive laparoscopic cameras.
10 The relatively low cost of the commercial embodiment of the present invention enables such training
11 simulators to be made widely available with minimal capital costs. Heretofore, such trainers could
12 not be implemented without the use of very expensive laparoscopic cameras.

13 5. I hereby further declare that all statements made herein of my own knowledge are true
14 and that all statements made on information and belief are believed to be true; and further, that these
15 statements were made with the knowledge that willful false statements and the like so made are
16 punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States
17 Code, and that such willful false statements may jeopardize the validity of the application or any
18 patent issued thereon.

19 Date: 2/19/09

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The Society of Laparroendoscopic Surgeons

INNOVATIONS OF THE YEAR 2004

The Society of Laparoendoscopic Surgeons Recognizes

Simulab Corporation

for

LapTrainer with SimuVision™

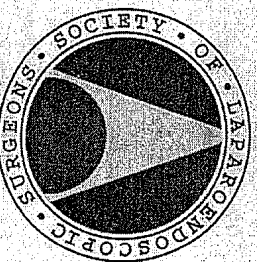
Selected for informational purposes only. SLS does not specifically endorse or approve any products. Surgeons should investigate any new equipment for safety and suitability for their particular practice and needs.

The 13th International Congress and Endo Expo 2004

September 29 - October 2, 2004

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